REMARKS

I. Introduction

Amended claim 1 is directed toward an endovascular support device (10) of a sinusoidal pattern having a plurality of substantially straight segments (16) connected end to end at a plurality of upper (12) and lower (14) axial turns or peaks. Claim 1 also precludes any joining or interconnection of the substantially straight segments in the central or intermediate portions thereof. The support device being capable of retaining a compressed configuration until delivered to the affected area within the vessel at which time the device is purposefully expanded by the application of a radial force to permanently place the device at the affected area.

Claims 4 and 5, and new claims 6 and 7, define a plurality of endovascular support devices or stent members (10), as discussed in the specification at column 6, lines 37-41. Again, each stent member (10) is formed of a sinusoidal pattern comprising a plurality of substantially straight segments (16) connected end to end at a plurality of upper (12) and lower (14) axial turns or peaks. The stent segments are mounted in an axially adjacent, non-overlapping manner on a catheter for delivery to the affected site. Each stent segment is capable of being retained in a compressed configuration until delivered to the affected area within the vessel at which time the stent segments are purposefully expanded by the application of a radial force to permanently place the stent segments at the affected area.

New claim 8 is similar to claim 1 except that it further limits the stent member to be carried by and on a balloon of a balloon catheter. And expanded upon inflation of the balloon.

New claim 9 further limits the degree of expansion of the stent member to be varied and controlled commensurate with the amount of inflation of the balloon. And is supported by the specification at page 8, lines 24-26 thereof.

In an Office Action dated September 29, 1997, claims 1, 4 and 5 were rejected under 35 U.S.C. § 102 (e) as anticipated by U.S. Patent Number 5,562,728 issued to Lazarus *et al.* (hereafter "Lazarus").

II. The Standard Of Anticipation

The standard for lack of novelty, or "anticipation," is one of strict identity. 1 Chisum, *Patents*, § 3.02 (1996). To anticipate a claim, a single reference must identically describe each and every element or step of the rejected claim. *See*, M.P.E.P. § 706.02(a) and § 2131. *See generally, Hybritech, Inc. v. Monoclonal Antibodies, Inc.*,231 U.S.P.Q. 81, 90 (Fed. Cir. 1986) ("It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention . . ."); *Atlas Powder Co. v.E.I. du Pont De Nemours & Co.*,224 U.S.P.Q. 409, 411 (Fed. Cir. 1984) ("exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference.").

Accordingly, Lazarus must disclose every element claimed in the instant invention to support a rejection under 35 U.S.C. § 102.

III. Lazarus Does Not Disclose Every Element Of The Claimed Invention

In rejecting claims 1, 4 and 5, the Examiner refers Applicant to Figures 10, 14 and 15

of Lazarus. *See* Office Action dated September 29, 1997 at page 2, paragraph 2. As will be discussed more fully below, Lazarus neither discloses every element contained in the independent claims, nor is it incapable of functioning in the manner claimed.

Lazarus discloses an endovascular grafting system. Graft 121 includes a deformable tubular member 122 and expandable spring means 131 at either end of member 122. These expandable spring means are self-expanding. In other words, under the spring force of helical coil springs 136, spring means 131 is urged radially outwardly towards the vessel wall.

Contrariwise, Applicant's claimed invention requires that the stent member retain a compressed configuration until acted on by a radial force *e.g.,* forcible expansion by inflation of a balloon.

Moreover, Lazarus' graft and self-expanding spring means are compressed and loaded into catheter 36. Clearly, as can be seen in Figures 1 and 14, spring means 131 is not mounted on the outer surface of catheter 36 as is specifically required by all pending independent claims.

Further, new claim 8 requires that the stent member be mounted on the inflatable member. In Lazarus, the spring means and graft are compressed onto the balloon shaft 62 (and not on the balloon 64) and loaded into the catheter 36. Balloon 64 is disposed distally or forwardly of the catheter 36 and spring means 131. As the catheter is withdrawn, "the graft 121 pops outwardly under the force of the spring means 131 . . ." *See* Lazarus at column 12, lines 3-4. The balloon 64 is then pulled rearwardly to position it into the proximal extremity of graft 121. The balloon is then inflated to drive hooks 151 into the vessel wall. This

procedure is illustrated with reference to Figures 1, 14 and 15.

Clearly, Lazarus does not disclose mounting spring means 131 on the outer surface of the catheter 36 nor on the outer surface of inflatable member 64. Additionally, spring means 131 "pop" out upon withdrawal of the catheter, as opposed to being caused to expand under the influence of inflation of the balloon.

Accordingly, Lazarus does not disclose every element of the independent claims, and therefore, it does not anticipate the claimed invention.

IV. Information Disclosure Statement

An Information Disclosure Statement ("IDS") is transmitted concurrently with this response. The references cited therein were uncovered in searches performed by Applicant after the filing date of the instant application. A brief description of the pertinence of each reference is included within the IDS.

Among the references cited in the IDS, is U.S. Patent No. 5,104,399 also issued to Lazarus. Both Lazarus '399 and Lazarus '728 applied by the Examiner, trace their roots to parent application Serial No. 559,935 filed December 9, 1983. The reason Applicant has cited Lazarus '399 is that Figures 10, 14 and 15 of Lazarus '728 were apparently added in a continuation-in-part application filed July 13, 1990, and therefore, would not be available prior art under 35 U.S.C. § 102(e). Whereas anchoring means 16 and 17 in Lazarus '399 apparently have an effective filing date of March 9, 1988.

V. The Remaining Prior Art

Of the remaining prior art cited by the Examiner *i.e.*, Gianturco *et al.*, Ersek and Caponigro, none disclose a stent member mounted on the outer surface of a catheter and capable of retaining its crimped configuration until application of a radially outwardly expanding force.

VI. Conclusion

In view of the foregoing, all claims pending are considered patentable over the art of record. Accordingly, reconsideration and allowance of this application is respectfully solicited.

Respectfully submitted,

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Date: Jan 29, 1998

Cynthia Benzerara